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The History of Rebates in the Drug Supply Chain and HHS' Proposed Rule to Change Safe Harbor Protection for Manufacturer Rebates

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I. Introduction

On February 6, 2019, the Department of Health and Human Services' Office of Inspector General (HHS-OIG) published a Proposed Rule that, if implemented, would fundamentally alter the current prescription drug rebate system.[1] The Administration's stated goal in Proposed Rule is to realign the incentives in negotiating drug manufacturer rebates and volume discounts with plan sponsors (and their contracted pharmacy benefit managers, or PBMs) to lower drug list prices and reduce beneficiary out-of-pocket cost sharing. The Proposed Rule seeks to implement these policy goals through changes to the regulatory safe harbors to the anti-kickback statute (AKS), which broadly prohibits financial arrangements to induce federal health care program business. First, the proposed rule would exclude from the discount safe harbor any discount or remuneration paid from a manufacturer to a Medicare Part D or Medicaid managed care plan unless the remuneration or discount was mandated by law. Second, the proposed rule would establish two new safe harbors: one protecting price reductions that are fully passed through at the point-of-sale, and a second protecting fixed fees paid from manufacturers to PBMs for services that meet specified criteria.

In the current drug pricing policy discussion, it is hard to overstate how significant a change this is to the AKS safe harbors, and transformative this proposal could be for the existing drug supply chain. The current rebate model has been in existence for close to 30 years. The Proposed Rule, if implemented, would lead to a new system in the Medicare Part D and Medicaid managed care programs with significant implications for manufacturers, health plans, pharmacy benefit managers, pharmacies, and more. The proposed rule would favor of upfront discounts for drugs so the savings can be applied to the price charged to the beneficiary at the point of sale. For stakeholders considering the impact of the Proposed Rule, this White Paper provides some history and context on the current rebate model. We begin by describing the Proposed Rule. Next, we describe the current rebate model that, we argue, has as its genesis three important events that happened in the 1990s. Finally, we offer some predictions if the Proposed Rule is ultimately finalized.

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[1] 84 Fed. Reg. 2,340 (Feb. 6, 2019).

II. The Trump Administration's Proposal to Change the Safe Harbor Protection of Drug Rebates

The February 2019 publication of a proposed rule to limit drug rebates by the Department Health and Human Services Office of Inspector General (HHS-OIG) is the culmination of a policy debate that has been gaining traction for nearly a year on how to lower drug prices, and reduce out-of-pocket spending by patients.

In May 2018, HHS released a policy statement and request for information (RFI) entitled, "HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs."[2] Among dozens of other policy considerations announced at that time, HHS argued in the Blueprint that higher rebates in Federal health care programs may be causing higher list prices in public programs (and also increasing the prices paid by consumers, employers, and commercial insurers).[3] In response to this concern, HHS asked what the agency should do to restrict or reduce the use of rebates. Among other policy ideas floated, HHS asked what incentives or regulatory changes (e.g., removing the discount safe harbor) could restrict the use of rebates and reduce the effect of rebates on list prices.

Echoing the policy concerns in the Blueprint, senior Administration officials have also publicly expressed concerns over the past year about the use of rebates in Federal health care programs and suggested alternative solutions centering largely on a proposal which would subject some or all rebates to Federal AKS scrutiny.[4] For example, on May 3, 2018 FDA Commissioner Scott Gottlieb in an address to the 2018 FDLI Annual Conference noted:

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[2] Id.

[3] Id. at 22,698 (Should Medicare Part D prohibit the use of rebates in contracts between Part D plan sponsors and drug manufacturers, and require these contracts to be based only on a fixed price for a drug over the contract term? What incentives or regulatory changes (e.g., removing the discount safe harbor) could restrict the use of rebates and reduce the effect of rebates on list prices? How would this affect the behavior of drug manufacturers, PBMs, and insurers?"). Ironically, the Blueprint was released merely days before the Medicare Trustees Report was published, in which the Trustees credited the current rebate system with lower Part D premiums. *See* 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Trust Funds at 34 (June 5, 2018).

[4] The federal anti-kickback statute, 42 U.S.C. § 1320a-7b, prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of federal health care program business. However, the statute also exempts certain conduct from kickback scrutiny, including "a discount or other reduction in price…", as well as "any payment practice specified by the Secretary in regulations…." See § 1320a-7b(b)(3). By regulation, CMS has adopted dozens of "regulatory safe harbors," including a safe harbor mirroring the statutory exception for discounts and explicitly referencing rebates as exempt from kickback scrutiny. See 42 C.F.R. § 1001.952(h). Absent safe harbor protection, a rebate paid by a manufacturer to a plan sponsor could be viewed as a "kickback" to the extent it

> "To take one example, one of the dynamics I've talked about before that's driving higher and higher list prices, is the system of rebates between payers and manufacturers. *And so what if we took on this system directly, by having the federal government reexamine the current safe harbor for drug rebates under the Anti-Kickback Statute*? Such a step could help restore some semblance of reality to the relationship between list and negotiated prices, and thereby boost affordability and competition."[5]

In remarks to the American Enterprise Institute on May 16, 2018, Secretary of HHS Alex Azar explained this policy further, noting:

> "We would welcome the PBM industry coming forth with broader proposals for moving away from today's system, including a plan for implementation with the pharmaceutical industry. But we also have the administrative power to end this system ourselves—to eliminate rebates and forbid remuneration from pharmaceutical companies, align interests, and end the corrupt bargain that keeps driving list prices skyward."[6]

In his comments before the Senate Health, Education, Labor & Pensions (HELP) Committee last Spring, Secretary Azar went further, noting: "Rebates are allowed under an exception to the AKS, and that's an exception that we believe by regulation we could modify."[7]

On February 6, 2019, the HHS-OIG published a Proposed Rule in the Federal Register which would exclude from the existing safe harbor that protects price reductions or other remuneration given by pharmaceutical manufacturers to Part D plans or Medicaid managed care organizations unless those discounts are a price reduction or discount mandated by law.[8] The Proposed Rule would also add two new safe harbors that would protect arrangements that do not exist in today's marketplace. The Administration believes the impact of these changes would likely be a new system of upfront discounts that can be passed on to the patient at the point of sale in lieu of currently administered retrospective rebates.

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is the intent of the manufacturer, in making payments to the plan, to cause additional units of its drugs to be purchased and reimbursed by federal health care programs.

[5] Speech by Scott Gottlieb, M.D., Commissioner of Food and Drugs. Keynote Address at the 2018 Food and Drug Law Institute Annual Conference, Washington, DC (May 3, 2018) (Emphasis added).
[6] Speech by Alex M. Azar II, Secretary of Health and Human Services. Address to AEI, Brookings USC Schaeffer, PBGH, and other policy and stakeholder groups, Washington, DC (May 16, 2018)
[7] Testimony of HHS Secretary Alex Azar before the Senate Health, Education, Labor and Pensions Committee (June 12, 2018).
[8] *See* 84 Fed. Reg. at 2363 (proposing revision to 42 C.F.R. § 1001.952(h)(5) and adding a new (h)(5)(viii) (Feb. 6, 2019)).

As we discuss below, the current rebate paradigm is the result of a confluence of three events that occurred in the 1990s: the adoption of the discount safe harbor to the AKS; a 1990s-era legal settlement that effectively foreclosed the use of upfront discounts; and a 1999 revision to the discount safe harbor that explicitly protected rebates. It is only in the context of this history that the Proposed Rule can be properly understood and assessed.

III. A Confluence of Events in the 1990s Led to the Current Rebate System

Under current practice, most manufacturers of branded drugs provide retrospective rebates to plan sponsors and their contracted PBMs based on the plans' members utilizing certain drugs at amounts that exceed certain market share metrics. As alluded to by now-FDA Commissioner Scott Gottlieb in a 2016 Forbes article,[9] the current rebate system in which some or all rebated amounts are correlated/conditioned on the amount of market share that a PBM can deliver dates back to the early 1990s.[10] Before that time, most manufacturers offered either upfront discounts on their products in exchange for greater volume and formulary access or else rebates *not* conditioned on volume – much like the type of upfront pricing now set forth in the Proposed Rule as a "solution" to rising drug prices.

But what led to this current model? As we have said, there were three key events in the 1990s that led to today's rebating model.

Safe Harbor Amendments. The first was the safe harbor amendments to the AKS itself. By the late 1980s, Congress had realized that the AKS was hindering innovation in health care plan design in the Medicare and Medicaid programs, and ran the risk of criminalizing conduct that was quite common in other sectors of the American economy. Accordingly, in 1987, Congress directed the Secretary of Health and Human Services to design a series of "safe harbors" under which certain practices would be immunized from prosecution under the AKS if the parties to the transaction adopted guardrails to prevent program abuse.[11] Shortly after President Reagan

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[9] Note that some observers dispute the claim, as made by Commissioner Gottlieb, that rebating as a practice originated in the mid-1990s litigation. What appears to be accurate is that while the practice of rebating predated this litigation, the now commonplace practice of rebates conditioned on market share/volume arose directly from this litigation, in an attempt to overcome barriers perceived to be imposed by antitrust laws.

[10] Scott Gottlieb, "How Congress Can Make Drug Pricing More Rational," Forbes (September 12, 2016). *See also* Health Care Financing Admin., *Study of Pharmaceutical Benefit Management Industry,* at 24 (June 2001) ("By 1994, the PBM business began to mature, and manufacturers were generally not recognizing the anticipated value from their contracting practices, despite the dramatic increases in total rebate payments. At the same time, pricing litigation placed manufacturers under scrutiny and caused them to become more discerning about conditions under which rebates would be paid. As a result, manufacturers made a fundamental change in their approach to contracting with PBMs. In general, rebate pricing criteria were changed so that PBMs would have to deliver increases in market share before all or most of the rebate would be paid.")

[11] "Medicare and Medicaid Patient and Program Protection Act of 1987," Pub. L. 100-93, 101 Stat. 680 (August 18, 1987).

signed this legislation, the Secretary delegated the authority to issue the safe harbors to the HHS Inspector General.[12]

Antitrust Litigation. Second, in 1994, hundreds of retail pharmacies filed a lawsuit (designated "In re Brand Name Prescription Drug Antitrust Litigation") against many, if not most, of the major wholesalers and brand manufacturers in the market at that time.[13] The lawsuit turned on a Depression-era antitrust law: the Robinson-Patman Act, 15 U.S.C. § 13(a). The Robinson-Patman Act makes it unlawful for a seller to differentially price a good or service based solely on the status of the buyer or purchaser where such an act prevents or inhibits competition.[14] In other words, the Robinson-Patman Act looks unfavorably upon certain price differentials that have the tendency to reduce, rather than promote, competition. The rationale supporting the illegality of such a practice is that price discrimination may give favored customers an edge in the market that has nothing to do with their superior efficiency.

In the lawsuit, the pharmacies argued that drug manufacturers and wholesalers conspired together in violation of the antitrust laws to refuse to offer the plaintiff pharmacies the same discounts on drug purchases that were offered to other purchasers, such as hospitals and health plans.

Eventually, many of the defendant manufacturers settled with the plaintiff retailers and, while not all of the specific terms of the settlement agreement are public, the judge presiding over the case approved an amended settlement agreement on June 21, 1996 that sufficiently addressed the plaintiff pharmacies' concerns about the pricing conduct of the defendant drug manufacturers.[15] In approving the amended settlement agreement, the Court articulated "two commitments which it felt to be appropriate on the part of the settling defendants: (1) That a manufacturer shall not refuse to discount its goods based solely on the status of the buying entity; and (2) To the extent that retail pharmacies and retail buying groups can demonstrate an ability to affect market share in the same or similar manner in which managed care entities are able, retailers will be entitled to the same types of discounts given to managed care entities for this reason."[16] The Court indicated that while "the language propounded by the amendment does not mirror precisely the language

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[12] 76 Fed Reg. 12,993 (April 20, 1988).
[13] See generally In re Brand Name Prescription Drugs Antitrust Litig., No. 94-C-897, 1996 Dist. WL 167350, at *10 (N.D. Ill. Apr. 4, 1996), opinion modified on reconsideration, No. 94 C 897, 1996 WL 351178 (N.D. Ill. June 24, 1996), and rev'd, 123 F.3d 599 (7th Cir. 1997).
[14] See 15 U.S.C. § 13(a).
[15] In re: Brand Name Prescription Drugs Antitrust Litigation, No. 94-C-897, 1996 U.S. Dist. LEXIS 8817 at *10 (N.D. Ill. June 21, 1996).
[16] Id. at 9-10.

articulated by the court we believe that the amendment sufficiently addresses our stated concerns and in fact represents a firm commitment on the part of the settling defendants."[17]

Amendment to Discount Safe Harbor. Third, in 1999, the HHS Inspector General further revised the discount safe harbor to explicitly treat a rebate as a permissible discount. The revised regulation defines a "rebate" as a discount which is fixed and disclosed to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of the sale.[18] As such, a rebate is granted after the sale has concluded and is applied retrospectively.

Thus, the current retrospective rebating practice in which rebated amounts are conditioned on a PBM moving a certain amount of market share became commonplace as a result of these three events: the adoption of the discount safe harbor; the settlement of the Robinson-Patman Act litigation, and the amendment to the discount safe harbor explicitly protecting rebates. The confluence of these three events thus allowed manufacturers to differentially price their products *without* violating the AKS or applicable antitrust laws.

In particular, the practice of retrospective rebating was designed to ensure that even retail pharmacies (as opposed to only health plans, PBMs, etc.) could also access beneficial discounts previously not offered to them. In order to settle the litigation, manufacturers agreed that "retail pharmacies and buying groups *that are able to demonstrate an ability to affect market share* will be entitled to discounts based on that ability, to the same extent that managed care organizations would get such discounts."[19]

IV. In Response to the Events of the 1990s, A New Rebate Paradigm Was Created

The events of the 1990s discussed above led drug manufacturers to change their approach to pricing. Manufacturers moved away from upfront, volume-based discounts and rebates not conditioned on volume to the use of retrospective rebates based on a PBM's or payer's ability to affect market share. As noted above, while the Robinson-Patman Act prohibits *some* differential pricing, it does not prohibit *all* differential pricing. In particular, section 2(b) of the Robinson-

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[17] Id at 9-11.
[18] 42 C.F.R. 1001.952(h)(4).
[19] Testimony of Sarah F. Jaggar, Director of Health Services Quality and Public Health before the House of Representatives Subcommittee on Oversight and Investigations Committee on Commerce (Sept. 19, 1996) (Emphasis added).
Not o all plaintiff pharmacies agreed to participate in the settlement. As a result, the litigation continued for these "opt-out" pharmacies, and lasted another 20 years. In 2015, in *Cash and Henderson Drugs, Inc. v. Johnson and Johnson*, 799 F.3d 202 (2nd Cir. 2015), the United States Court of Appeals for the Second Circuit addressed the contentions of the non-settling pharmacies. In a narrow ruling, the Second Circuit concluded that the pharmacies had failed to carry their burden of proof to show competitive injury. Importantly, however, the Court did not thereby sanction the practice of differential discounts; it merely concluded that in this instance, the pharmacies had not met their legal burden in a motion for summary judgment.

Patman Act permits the use of price differentials to meet competition from sellers which are offering discounts to specific customers.[20] In other words, while a seller cannot offer differential pricing for *no reason*, it may do so if there are real, functional differences among purchasers – such as the ability of a purchaser to move market share.

Unlike an upfront discount, a rebate gives a health plan or other purchaser the ability to first demonstrate the ability to move market share, and only then receive a discount on the price offered. Thus, to incent manufacturers to lower prices, and to avoid antitrust pitfalls, payers acting on behalf of government and commercial plans needed to wait for price reductions after pharmacy dispensing and after the manufacturers verified that the payers met volume or share requirements.

Before his appointment as FDA Commissioner, Scott Gottlieb explained this change in testimony before the Senate. His testimony addressed the question: "Why, in other words, does the discounting in the drug space take the form of rebates paid to pharmacy benefit managers through a convoluted system on the retrospective of the transaction, rather than an upfront discount on the drugs?"[21] Gottlieb testified that "[i]t all stems from litigation in the late 1990s … [t]o get around this outcome, the drug makers moved away from offering discounts and toward today's model of rebates."[22]

V. Considerations as the Proposed Rule is Reviewed

All parties in the prescription drug supply chain – manufacturers, wholesalers, health plans, PBMs, pharmacies and patients – will need to adapt if the Proposed Rule is finalized. In this section of the paper, we have identified six key issues to watch as HHS-OIG considers comments on the Proposed Rule:

1) With no more protection for rebates in the discount safe harbor, will manufacturers and payers continue the existing rebating model, and rely on the statutory discount safe harbor or other AKS safe harbors?

2) How will the parties in the supply chain assess their antitrust risk under the new discounting model in light of the settlement of the 1990s litigation?

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[20] 15 U.S.C. § 13(b). See also Texaco Inc., v. Hasbrouck. 496 U.S. 543, 562 (1990) (permitting price differentials based on the real functional differences among purchasers).

[21] S. Gottlieb, Resident Fellow at American Enterprise Institute, Statement before the Senate Comm. on Health, Education, Labor and Pensions, *EpiPen Price Increases, How Regulatory Barriers Inhibit Pharmaceutical Competition* (Oct. 7, 2016), at 11.

[22] Gottlieb, *supra* n. 5. ("It's the outcome of a two-decade old dispute that forced drug makers to try and conceal just how much they discounted off the medicines that they were selling to health plans. . . . To work around the litigation, and the settlement they struck with the pharmacies, drug makers came up with a rebate scheme rather than offering discounts up front.").

3) Will premiums in the Part D program increase under the new model?

4) Will out-of-pocket expenses decline at the pharmacy counter?

5) What is the future of value-based purchasing arrangements?

6) What is the future of supplemental rebates in the Medicaid program?

These, and other questions, should be front-and-center for policymakers as they debate the relative merits of the Proposed Rule and, if implemented, its impact on the future of the drug supply chain.

VI. Conclusion

As discussed in this White Paper, the current rebate model has been in existence for close to 30 years. In that time period a series of events – the 1987 amendments to the AKS, the 1990s Robinson-Patman Act litigation, and the 1999 changes to the discount safe harbor – resulted in the rebating system under which manufacturers, health plans, and PBMs largely rely on today. As policymakers and stakeholders consider the future of the drug supply chain, this history acts as an important guidepost and context for the Proposed Rule under consideration today.